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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/069,228	04/27/98	PLOWMAN G	234/118

022249
LYON AND LYON LLP
SUITE 4700
633 WEST FIFTH STREET
LOS ANGELES CA 90071-2066

HM12/0914

EXAMINER	
HOLLERAN, A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 09/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/069,228	Plowman et al.
Examiner	**Group Art Unit**
Anne Holleran	1642

☒ Responsive to communication(s) filed on *Jul 12, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *2-7, 9, and 23-37* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2-7, 9, and 23-37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5, 6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election, without traverse, of Group I, claims 1-9 in Paper No. 8, filed July 12, 1999, is acknowledged. Claims 1, 8 and 10-22 were canceled. Claims 23-37 were added.

2. Claims 2-7, 9 and 23-37 are pending.

Claims 2-7, 9 and 23-37 are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-7, 9 and 23-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 9, 23, 24, 25 and 35 are vague and indefinite in the recitations " ALK-7 polypeptide". The metes and bounds of the claims cannot be determined given the open definition of ALK-7 polypeptide (page 17, lines 13-15).

Claims 2, 23 and 24 are vague and indefinite in the recitation "complement" of a nucleic acid molecule. Given its broadest possible interpretation, the term "complement" includes nucleic acid molecules that are not as long as the sequence to which they are complementary and sequences that are complementary at their termini but have a loop region in the middle. Replacing the term "complement" to "a nucleic acid that is completely complementary" or "a nucleic acid that is fully complementary" would obviate this rejection.

Claim 2 is vague and indefinite in the recitation "highly stringent conditions." On page 9, lines 2-19, the specification discloses that the term "highly stringent conditions" "...may mean...". Therefore, the claim is indefinite, since "stringent conditions" is not defined with clear metes and bounds.

Claim 23(subpart "c") is vague and indefinite. It is not clear if Claim 23 is drawn to nucleic acid molecules encoding a polypeptide comprising all of the regions of SEQ ID NO:2 listed, or to nucleic acid molecules encoding fragments comprising any one of the regions specified. The specification contains the same recitation (page 10, lines 23 and 24) and does not clarify the claim.

Claim 23 is vague and indefinite because there is no support in the specification or the claims as originally presented for the recitation "193-489". In the specification, motifs are specified, one of which is "193-485" of SEQ ID NO: 2. In the claims, as originally presented, and in the specification (page 10, line 20) the segment "193-483" is recited. Therefore, it is not clear which segment is intended.

Claim 2, 23, 24, 35 and 37 are vague and indefinite in the recitation "having" because it is not clear if Applicant intends open or closed language. For examination purposes, the term "having" will be interpreted as open language.

Claims 6 and 7 are vague and indefinite. Claims 6 and 7 are drawn to nucleic acid probes whose sequences are not described. The claims do not specify the metes and bounds of the claimed probes because the specification (page 12, line 26 - page 13, line 2) provides a definition that does not provide metes and bounds. Furthermore, Claims 2, 23 and 24 have been found to be vague and indefinite. Therefore, the recitation "for the detection of nucleic acid of Claim 2, Claim 23 or Claim 24" does not provide adequate structural information.

Claim 7 is vague and indefinite due to improper antecedent basis. Claim 7 recites "wherein said polypeptide" and refers to Claim 6. Claim 6 contains no recitation of "polypeptide".

Claim 27 is vague and indefinite in the recitation "corresponding". It is not clear if the recitation is open or closed. For examination purposes, "corresponding" will be interpreted to be open language. It is also not clear if the nucleic acid molecule of Claim 27 comprises a nucleic acid that is the same as that of SEQ ID NO: 1 or if it comprises a nucleic acid that is similar to that of SEQ ID NO: 1.

Claims 36 and 37 are vague and indefinite in the recitation ALK-7DN and ALK-7TD. ALK-7DN and ALK-7TD are laboratory designations and are not specifically tied to amino acid or nucleotide sequences.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 (added by amendment) is drawn to nucleic acid molecules that encode ALK-7 polypeptides comprising the full length amino acid sequence as set forth in SEQ ID NO: 2, except that it lacks one or more, but not all of the following segments of amino acid residues of SEQ ID NO: 2 1-25, 26-113, 114-493, 193-489. As discussed above, there is no literal support in the specification or in the claims as originally presented for the interval of SEQ ID NO: 2 193-489. Therefore, Claim 23 introduces new matter into the specification.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 9, 23, 24, 28 and 37 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 23, 24 and 37 are directed to nucleic acid molecules without a recitation indicating the hand of man. Therefore, Claims 23, 24 and 37 read on naturally occurring nucleic acid molecules encoding ALK-7 polypeptides. Dependent Claims 28 and 9 also read on naturally occurring nucleic acid molecules and cells which contain the gene encoding ALK-7 polypeptides.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 2-7, 9, 27-33 are rejected under 35 U.S.C. 102(e) as being anticipated by either US Patent 6,614,609 ("Ibanez et al.,'609" filed 15 Nov 1994), US Patent 5,789,565 ("Ibanez et al,'565" effective US filing date 15 Nov 1994) or US Patent 5,811,245 (Ibanez et al,'245" effective US filing date 15 Nov 1994).

Claim 2 is drawn to an isolated, enriched or purified nucleic acid molecule encoding an ALK-7 polypeptide, wherein said nucleic acid molecule comprises a nucleotide sequence that encodes a polypeptide comprising the full length amino acid sequence set forth in SEQ I D NO: 2, is the complement of said nucleotide sequence or hybridizes to the complement of said nucleotide sequence and encodes an ALK-7 polypeptide. Dependent Claim 3 is drawn to the nucleic acid molecule which is isolated, enriched or purified from a mammal. Dependent Claim 5 (from Claim 2) further comprises a vector or promoter effective to initiate transcription in a host cell. Dependent Claims 29-31, and 33 (dependent from Claim 5) add limitations reciting specific vectors, promoters and host cells. Dependent Claim 32 (dependent from Claim 31) adds a limitation reciting specific mammalian cell types

Claims 23 and 24 are drawn to nucleic acid molecules encoding or the complements of specified fragments or domains or combinations of fragments or combinations of domains of SEQ ID NO: 2. Given the broad definition of complementary nucleotides, complements may be interpreted as sequences smaller than the specified fragments or domains or combinations of fragments or combinations of domains of SEQ ID NO: 2.

Claims 6 and 28, multiply dependent from Claim 2, Claim 23 or Claim 24, are drawn, respectively, to a nucleic acid probe and a nucleic acid molecule further comprising restriction endonuclease recognition sites at the 5' end and/or 3' end. Dependent Claim 7 (dependent from Claim 6) adds the limitation that the minimum size of the probe must be 18 nucleotides. Claim 9, multiply dependent from Claim 2, Claim 23 or Claim 24, is drawn to a recombinant cell comprising a nucleic acid molecule encoding either the ALK-7 polypeptide of Claim 2, Claim 23 or Claim 24 or the ALK-7 polypeptide of Claim 2, Claim 23 or Claim 24 fused to a non-ALK-7 polypeptide.

Independent Claim 27 is drawn to an isolated, enriched or purified nucleic acid molecule encoding an ALK-7 polypeptide comprising the nucleotide sequence of SEQ ID NO: 1 or a sequence similar to that of SEQ ID NO: 1.

Either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose SEQ ID NO: 1 which is a nucleic acid molecule which would hybridize to the complement of a nucleotide sequence which encodes a polypeptide comprising the full length amino acid sequence of SEQ ID NO: 2 (see sequence alignment). SEQ ID NO: 1 of either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 is similar to the nucleotide sequence set forth in SEQ ID NO: 1 of the instant application (see sequence alignment). Thus, any of Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose a nucleic acid molecule which is the same as that of Claims 2 and 27.

Either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 teach isolation of ALK-7 nucleic acids (including that of SEQ ID NO: 1) from humans and rats (column 7, lines 46-61 and

column 24, lines 10-32). Thus, any of Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 teach a nucleic acid molecule which is the same as that of Claims 3 and 4.

Either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose the nucleic acid molecule of Claim 2 further comprising a vector (column 25, lines 31-33) co-transfected into NIH/3T3 cells. Either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 also teach the nucleic acid molecule of Claim 2 incorporated into vectors such as pBR322, ColE1, or pSC101 (column 16, lines 34 - 47) and the nucleic acid molecule operably linked to promoters such as the bla promoter of the β-lactamase gene sequence of pBR322 (column 14, lines 12-32). Either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 also teach the nucleic acid molecule of Claim 2 in a eukaryotic host cell wherein the promoter is, for example, the promoter of the mouse metallothionein I (column 15, lines 49-61). Thus, any of Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose a nucleic acid molecule which is the same as that of Claims 5, 9, 29-33.

Either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose the nucleic acid molecule of Claim 2 further comprising restriction endonuclease sites a the 5' and 3' end (column 24, lines 10-32). Thus, any of Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose a nucleic acid molecule which is the same as that of Claim 28.

Either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose nucleic acid molecules which may be used as probes (see column 24, lines 10 - 13, nucleic acid molecules encoding VAFKIF) and which would be complementary to the nucleic acid molecules of Claims

23 and 24. Thus, any of Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 disclose nucleic acid molecules which are the same as that of Claims 6, 7, 23 and 24.

11. Claims 2, 3, 5-7, 9, 23, 24, and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Ryden et al (see page 30604, Ryden, M. et al., J. Biol. Chem. 271(48): 30603-30609, 1996.

The subject matter of Claims 2, 3, 5-7, 9, 23, 24, 29 and 32 have been discussed above. Ryden et al disclose the deduced amino acid sequence of ALK-7 and teach the cloning of the DNA encoding ALK-7 and the expression of the mRNA encoding ALK-7. The cDNA was isolated from rat brain. A PCR probe, degenerate primers encoding the region VAFKIF was disclosed. Cos cells were disclosed as host cells for the nucleic acid molecules encoding ALK-7. Thus, Ryden et al disclose nucleic acid molecules and host cells which are the same as that claimed.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 in view of US Patent 5,168,050 (Hammonds, Jr. et al, US Patent 5,168,050, publication date 1 Dec. 1992).

Claim 34 is drawn to a nucleic acid molecule of Claim 2 further comprising a vector, either pAdRSVOES or pRK5. Neither Ibanez et al., '609, Ibanez et al.,'565 nor Ibanez et al,'245 teach the nucleic acid molecule of Claim 2 further comprising pAdRSVOES or pRK5 vectors. However, the eukaryotic vector, pRK5 is known in the art. Hammonds, Jr. et al disclose cloning a BMP-3 nucleic acid molecule into a pRK5 expression plasmid (column 12, lines 47-51) which is an expression plasmid suitable for transfection into mammalian host cells. One of ordinary skill in the art would have been motivated to combine the teachings of Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 with the disclosure of Hammonds, Jr. et al because Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 teach that expression of recombinant proteins in mammalian host cells ensure "native" glycosylation (column 15, lines 3-15). Hammonds, Jr. et al also teach the general usefulness of using mammalian organisms as expression hosts (column 6, lines 7-30). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 with the disclosure of Hammonds, Jr. et al to make the claimed invention.

Conclusion

No claims are allowed. Claims 25, 26, and 35-37 are free of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D. can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
September 13, 1999

Nancy A Johnson
Primary Examiner